

REMARKS

The Office Action of July 13, 2007 rejected claims 1-12 and 14-15 under 35 U.S.C. §112. In addition, claims 1-12 and 14-15 were rejected under both 35 U.S.C. §102 and §103. Applicant has addressed each and every objection and ground for rejection in the Office Action dated July 13, 2007 (Paper No. 20070700).

Applicant submits that in view of the amendments made to the claims in view of the remarks set forth below, the claims as currently presented are allowable. As such, Applicant respectfully requests removal of the rejections set forth in the Office Action of July 13, 2007 and allowance of the presently submitted claims.

I. Rejections Under 35 U.S.C. §112

The Office Action of July 13, 2007 rejected claims 1-12 and 14-15 under 35 U.S.C. §112, first paragraph, for failing to comply with the written description requirement. The Office Action states “[t]he phrase ‘kallikrein production inhibition activity’ was not described in the specification as originally filed. The specification described a ‘kallikrein protease inhibition activity’, which appears to be describing an activity that inhibits kallikrein protease. The new phrase ‘kallikrein production inhibition activity’ appears to describe an activity that inhibits production of kallikrein, which is a different activity than inhibiting a kallikrein protease.”

Applicant respectfully submits that the original translation of the term “血管舒缓素抑制” was incorrect from the original application, and that the proper translation from the application filed as PCT/CN2003/000923 on October 30, 2003, and published as WO 2004/060381 A1, is “kallikrein production inhibition activity.” Applicant respectfully requests removal of this rejection in light of Applicant’s statement that the initial translation was incorrect and the concurrently submitted declaration of Inventor Cheung. See *In re Oda*, 443 F.2d 1200, 170 U.S.P.Q. 268 (C.C.P.A.. 1971).

Claims 14 and 15 were rejected in the Office Action as being indefinite for their use of “extract of the rabbit skin.” Claims 14 and 15 have been amended to depend from claim 1 to further describe the extract and how it is produced. Applicant submits that the claims as amended are in condition for allowance and respectfully request removal of this rejection.

Claim 1 and its dependent claims were rejected in the Office Action as being vague and indefinite for reciting “feeding rabbit vaccinated with vaccinia virus.” In addition, the Office Action rejected the term “sufficiently inflamed,” stating that the term is unclear. Applicant has also amended Claim 11 to clarify the term “sufficiently inflamed.” The Office Action also rejected Claim 6 for reciting “~” instead of “-“ and Claim 11 for utilizing the term “SART.” Applicant has amended the claims to clarify the objections raised in the Office Action and submit that the rejections have been overcome through amendment.

## II. Rejections Under 35 U.S.C. §102

The Office Action rejected Claims 1-12 under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,057,324 to Shibayama et al. ("Shibayama"). The Office Action stated that Shibayama "teaches a rabbit skin extract that has inhibitory activity against kallikrein formation, wherein the substance is useful as a drug (abstract). The substance is obtained by infecting a rabbit skin with a vaccinia virus (col. 1, line 45-65) and removing the skin (example 1). Shibayama teaches the extract in a drug composition with a pharmaceutically acceptable carrier (claims)." The Office Action admits, however, that "the reference does not expressly teach all of the limitations regarding how the rabbit skin is produced." See Office Action at page 7.

Applicant respectfully submits that Shibayama is distinct from the presently claimed subject matter and is allowable in view of Shibayama. As an example, the selection of vaccinia in the present invention provides more choices to vaccinate the rabbit skin to gain the active substance. Previously, only the Lister strain could be used to vaccinate the rabbit skin. Under the presently claimed subject matter, however, several stains are disclosed and numerous experiments have been conducted of different strains of the vaccinia virus. Indeed, the present invention involves certain strains exhibiting characteristics similar to that of the Lister strain, which is most often used by those of ordinary skill in the art.

Shibayama does not disclose the various strains disclosed in the presently claimed Claims 2-6. Moreover, Shibayama does not disclose the various rabbit varieties

utilized or the process of inoculation to form the rabbit skin utilized in the presently claimed subject matter. The Office Action stated that “the prior art discloses a product which reasonably appears to be identical with or slightly different than the claimed product-by-process.” See Office Action at page 7. Applicant has amended Claim 1 and submits that the remaining claims depend from Claim 1.

Applicant has amended Claim 1 to clarify the process by which rabbit skins in accordance with the present invention are formed. In particular, rabbit skins of the present invention utilize a particular process for fractionating the eluted liquid: fractionation based on molecular weight. In contrast, Shibayama specifically teaches away from this method, and utilizes a method of distilling at 60°C under decompression. With regard to fractionation, Shibayama states “[a]lthough the results are not shown herein, other fraction than the substance of the present invention, which is fractionated by ultrafiltration, had scarcely shown the inhibitory action against the formation of kallikrein.” Shibayama, col. 4, lines 34-39. As such, Shibayama does not teach the same method as disclosed in the presently submitted claims. Applicant respectfully requests removal of the rejections and allowance of the claims as amended.

### III. Rejections Under 35 U.S.C. §103

The Office Action also rejected Claims 1-12 and 14-15 under 35 U.S.C. §103, as being obvious in view of Shibayama. Applicant respectfully submits that, as demonstrated

above, the presently claimed subject matter differs substantially from Shibayama. Shibayama does not disclose, teach or suggest the various strains presented in the presently claimed subject matter. Moreover, Shibayama does not disclose, teach or suggest the various rabbit varieties utilized or the process of inoculation described in the presently claimed subject matter. In fact, Shibayama teaches away from the specific fractionation method taught in the presently claimed subject matter. Shibayama specifically stated that the fractionation used in Shibayama "has scarcely shown inhibitory action" for the same process of the presently claimed inhibitory action. As such, there is no disclosure, suggestion or teaching in Shibayama to use the processes described in the presently amended claims.

Applicant has amended Claims 1-12 and 14-15. Applicant submits that the amended claims are allowable over the rejections set forth in the Office Action of July 13, 2007. As such, Applicant respectfully requests allowance of the claims and removal of all rejections.

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CONCLUSION

In view of the above-identified amendments and remarks, Applicant respectfully submits that the claims in their present form are allowable over the issues raised in the Official Action mailed July 13, 2007. In the event that there are further issues which may be resolved by a telephone interview, the Examiner is urged to contact Applicant's undersigned Attorney at the telephone number listed below.

Respectfully submitted,

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